Application No. 10/010,968

AMENDMENTS TO THE CLAIMS

A detailed listing of all claims that are, or were, in the present application, irrespective of whether the claim(s) remains under examination in the application are presented below. The claims are presented in ascending order and each includes one status identifier. Those claims not cancelled or withdrawn but amended by the current amendment utilize the following notations for amendment: 1. deleted matter is shown by strikethrough for six or more characters and double brackets for five or less characters; and 2. added matter is shown by underlining.

1.-2. (Cancelled)

3. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

a storage structure adapted to hold a plurality of radioisotope seeds;

a needle assembly;

a Z-axis automated motion control system that selectively moves at least the needle assembly along an insertion axis and into the patient and selectively ejects radioisotope seeds from the storage structure into the needle assembly; and

an X-Y axis automated motion control system that selectively moves at least the needle assembly in a plane perpendicular to the insertion axis to selectively position the insertion axis relative to the patient.

4. (Currently Amended) [The automated implantation system of claim 3] An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

a storage structure adapted to hold a plurality of radioisotope seeds;

a needle assembly;

a Z-axis automated motion control system that selectively moves at least the needle assembly along an insertion axis and into the patient and selectively ejects radioisotope seeds from the storage structure into the needle assembly; and

an X-Y axis automated motion control system that selectively moves at least the needle assembly in a plane perpendicular to the insertion axis to selectively position the insertion axis relative to the patient,

wherein the storage structure is a replaceable cartridge and the system include cartridge receiving structure defined along at least a portion of the insertion axis.

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5. (Original) The automated implantation system of claim 4 wherein the Z axis automated motion control system moves the cartridge and the needle assembly together to maintain a relative position between the cartridge and the needle assembly along the insertion axis.

6. (Currently Amended) The automated implantation system of claim [[3]] 4 wherein the automated implantation system further comprises:

a computer processor operably connected to at least the Z-axis automated motion control system and the X-Y axis automated motion control system and having a user interface that displays information about the automated implantation system and accepts commands from a user to control the process of implanting the plurality of radioisotope seeds in the patient.

7. (Original) The automated implantation system of claim 6 wherein the user interface displays a grid identifying a plurality of locations that are selectable by the user in the plane perpendicular to the insertion axis where radioisotope seeds are to be implanted and the computer processor controls the X-Y axis automated motion control system to position at least the needle assembly perpendicular to a location selected by the user.

8. (Original) The automated implantation system of claim 7 wherein computer process selectively rotates the grid within the plane perpendicular to the insertion axis so as to simulate a rotation of the needle assembly with respect to the plane perpendicular to the insertion axis and then recomputes the locations selected by the user in response to the rotation to achieve the rotation without requiring that the needle assembly be physically rotated in the plane perpendicular to the insertion axis.

9. (Original) The automated implantation system of claim 6 wherein the user interface includes at least one direction control input mechanism that allows a user to selectively control at least the Z-axis automated motion control system to control movement of at least the needle assembly along the insertion axis and into the patient.

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10. (Original) The automated implantation system of claim 9 wherein the direction control input mechanism is a joystick.

11. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

a storage structure adapted to hold a plurality of radioisotope seeds;

a needle assembly;

an ultrasound probe;

a first Z-axis automated motion control system that selectively moves at least the needle assembly along an insertion axis and into the patient and selectively ejects radioisotope seeds from the storage structure into the needle assembly;

a second Z-axis automated motion control system that selectively moves the ultrasound probe in a probe axis generally parallel to the insertion axis; and

a computer processor operably connected to at least the second Z-axis automated motion control systems and to the ultrasound probe such that the computer processor utilizes the ultrasound probe to monitors a position of an organ being treated in the brachytherapy procedure and selectively adjusts a base plane position of the insertion axis relative to the organ.

12. (Original) The automated implantation system of claim 11 wherein the computer processor automatically adjusts the base plane in response to a movement in the position of the organ during the brachytherapy procedure.

13. (Original) The automated implantation system of claim 11 wherein the computer processor adjusts the base plane in response to a user directive and all subsequent radioisotope

seeds placed by the implantation systems are placed at a depth determined from the adjusted base plane position.

14. (Original) The automated implantation system of claim 11 further comprising:

autofocus system operably connected to the ultrasound probe and the second Z axis automated motion control system such that the computer processor utilizes the autofocus system to automatically adjust the base plane position.

15. (Cancelled)

16. (Currently Amended) The automated implantation system of claim [[15]] 18 wherein the implantation station further comprises:

an X-Y axis automated motion control system that selectively moves at least the needle assembly in a plane perpendicular to the insertion axis; and

wherein the computer processor captures and stores an image from the ultrasound probe each time the needle assembly is located at a different position in the plane perpendicular to the insertion axis by the X-Y axis automated motion control system.

17. (Currently Amended) The automated implantation system of claim [[15]]18 wherein the computer processor captures and stores the at least one image from the ultrasound probe when the needle assembly is moved forward along the insertion axis to a distal most location where radioisotope seeds will be placed.

18. (Currently Amended) [The automated implantation system of claim 15 wherein the computer processor further includes] An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

a storage structure adapted to hold a plurality of radioisotope seeds;

a needle assembly;

a Z-axis automated motion control system that selectively moves at least the needle assembly along an insertion axis and into the patient and selectively ejects radioisotope seeds from the storage structure into the needle assembly;

an ultrasound probe; and

a computer processor operably connected to the Z-axis automated motion control systems and to the ultrasound probe that captures and stores at least one image from the ultrasound probe with the needle assembly in position in the patient to selectively place at least one radioisotope seed so as to form a record of the brachytherapy procedure and including a user interface that displays information about the automated implantation system and accepts commands from a user to control the process of implanting the plurality of radioisotope seeds in the patient and wherein images from the ultrasound probe are displayed on the user interface in a separate window on the user interface.

19. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

a storage structure adapted to hold a plurality of radioisotope seeds;

a needle assembly;

a first Z-axis automated motion control system that selectively moves at least the needle assembly along an insertion axis and into the patient and selectively ejects radioisotope seeds from the storage structure into the needle assembly;

an ultrasound probe;

a second Z-axis automated motion control system that selectively moves the ultrasound probe in a probe axis generally parallel to the insertion axis; and

a computer processor operably connected to at least the second Z-axis automated motion control system that executes an autocalibration routine that automatically calibrates the second Z-axis automated motion control system prior to utilizing the ultrasound probe in the brachytherapy procedure.

20. (Original) The automated implantation system of claim 19 wherein the ultrasound probe is replaceable and the computer processor determines an XYZ relationship of the ultrasound sound probe to the needle assembly each time a different replaceable ultrasound probe is used with the automated implantation system.

21. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

a storage structure adapted to hold a plurality of radioisotope seeds;

a needle assembly including a needle coaxially located within a canula;

a needle automated motion control system that controls the needle; and

a canula automated motion control system that controls the canula separately from the needle,

such that the needle automated motion control system and the canula automated motion control system cooperate to initially move the needle and canula along an insertion axis and into the patient and the needle automated motion control system withdraws the needle to selectively ejects radioisotope seeds from storage structure into the canula.

22. (Original) The automated implantation system of claim 21 wherein the needle automated motion control system and the canula automated motion control system initially move the needle and canula along the insertion axis by repetitively advancing the needle a distance beyond the canula and then advancing the canula that same distance.

23. (Original) The automated implantation system of claim 22 wherein the distance the needle automated motion control system advances the needle beyond the canula ranges between 0.5 and 2.0 cm.

24. (Original) The automated implantation system of claim 21 wherein the canula automated motion control system withdraws the canula once all the radioisotope seeds are positioned in the patient with the needle automated motion control system keeping the needle in place until the canula is withdrawn.

25. (Original) The automated implantation system of claim 21 wherein the storage structure further includes a plurality of spacers and wherein the needle automated motion control system selectively ejects a radioisotope seed and a spacer into the canula as a pair oriented longitudinally along the insertion axis and advances the pair along the insertion axis by pushing on the spacer with the needle.

26. (Original) The automated implantation system of claim 25 wherein the needle automated motion control system withdraws the needle once the canula is positioned as desired to accept a plurality of pairs each consisting of a radioisotope seed and a spacer in the canula and each pair is moved along the insertion axis to a staging area in the canula proximal to a distal end of the canula until all of the pairs for a current location of the canula are in the staging area after which the needle automated motion control system advances all of the pairs along the insertion axis to the distal end of the canula.

27. (Original) The automated implantation system of claim 26 wherein the canula automated motion control system withdraws the canula once all the pairs are positioned at the distal end of the canula with the needle automated motion control system keeping the needle in place until the canula is withdrawn.

28. (Original) The automated implantation system of claim 26 wherein the canula includes at least one annular wiping seal positioned along the insertion axis at an end of the staging area.

29. (Original) The automated implantation system of claim 21 wherein the needle automated motion control system and the canula automated motion control system comprise a pair of synchronized lead screw drives.

30. (Original) The automated implantation system of claim 21 wherein the needle automated motion control system comprises a capstan drive system and the canula automated motion control system comprises a lead screw drive.

31. (Original) The automated implantation system of claim 21 wherein the needle is selectively replaceable in the needle automated motion control system.

32.-37. (Cancelled)

38. (Currently Amended) [The automated implantation system of claim 37 wherein the targeting indication system includes] An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

a storage structure adapted to hold a plurality of radioisotope seeds;

a needle assembly;

a Z-axis automated motion control system that selectively moves at least the needle assembly along an insertion axis and into the patient and selectively ejects radioisotope seeds from the storage structure into the needle assembly;

a targeting indication system that demarks a location of where the insertion axis is positioned on the patient during the brachytherapy procedure; and

at least a plurality of light emitting devices that generate a corresponding plurality of light beams on the location.

39. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

a storage structure adapted to hold a plurality of radioisotope seeds;

a needle assembly;

a Z-axis automated motion control system that selectively moves at least the needle assembly along an insertion axis and into the patient and selectively ejects radioisotope seeds from the storage structure into the needle assembly; and

a base station that supports at least the Z-axis automated motion control system and the needle assembly and positions the insertion axis relative to the patient, the base station including:

a base;

a moveable assembly that includes the insertion axis and is orientable independently of the base; and

a stand operably connected between the base and the moveable assembly.

40. (Original) The automated implantation system of claim 39 wherein the stand includes:

a gross vertical adjustment mechanism that adjusts a vertical height of the moveable assembly relative to the base;

a rotation mechanism that pivots the moveable assembly about a vertical axis relative to the base;

a lateral positioning mechanism that adjusts a lateral position of the moveable assembly in relation to the vertical axis; and

a tilt mechanism that tilts the moveable assembly relative to a horizontal plane perpendicular to vertical axis.

41. (Original) The automated implantation system of claim 40 wherein at least the gross vertical adjustment mechanism is motorized.

42. (Original) The automated implantation system of claim 39 wherein the base includes a set of retractable wheels that allows the implantation system to be moved when the wheels are extended and provide a stable position for the implantation system when the wheels are withdrawn.

43. (Original) The automated implantation system of claim 39 wherein the base station includes alternative power sources, a primary power source that plugs into an external outlet and a secondary power source connected to a battery housed in the base station, the secondary power source configured to replace the primary power source in the event that the primary power source is unplugged from the external outlet.

44. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

a storage structure adapted to hold a plurality of radioisotope seeds;

a needle assembly;

an ultrasound probe having an outer rigid sheath coaxial with the ultrasound probe;

a first Z-axis automated motion control system that selectively moves at least the needle assembly along an insertion axis and selectively ejects radioisotope seeds from the storage structure into the needle assembly;

a second Z-axis automated motion control system that selectively moves the ultrasound probe in a probe axis generally parallel to the insertion axis such that the second Z-axis automated motion control system initially positions both the outer sheath and the ultrasound probe in the patient and then moves only the ultrasound probe along the probe axis and within the sheath to generate ultrasound images along the probe axis.

45. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

cartridge receiving structure adapted to receive a cartridge containing a plurality of radioisotope seeds;

a needle assembly;

carrier receiving structure adapted to receive a carrier structure containing an ultrasound probe;

a first Z-axis automated motion control system that selectively moves at least the needle assembly along an insertion axis and selectively ejects radioisotope seeds from the storage structure into the needle assembly;

a second Z-axis automated motion control system that selectively moves the ultrasound probe in a probe axis generally parallel to the axis of insertion.

46. (Original) The automated implantation system of claim 45 wherein the carrier structure includes a mechanism to allow for rotation of the ultrasound probe relative to the probe axis and to selectively lock the ultrasound probe in a desired rotation.

47. (Original) The automated implantation system of claim 45 wherein the needle assembly and the cartridge are operably arranged in a common carrier structure and the carrier structure mates with a cartridge receiving structure.

48. (Original) A method of operating an automated implantation system having a Z-axis automated motion control system and an X-Y axis automated motion control system that control at least a needle assembly for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

(a) using the X-Y axis automated motion control system to position an insertion axis of the needle assembly relative to the patient;

(b) using the Z-axis automated motion control system to selectively move the needle assembly along the insertion axis to implant at least one radioisotope seed; and

(c) repeating steps (a) and (b) for a plurality of locations on a base plane perpendicular to the insertion axis.

49. (Currently Amended) [The method of claim 48] A method of operating an automated implantation system having a Z-axis automated motion control system and an X-Y axis automated motion control system that control at least a needle assembly for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

(a) using the X-Y axis automated motion control system to position an insertion axis of the needle assembly relative to the patient;

(b) using the Z-axis automated motion control system to selectively move the needle assembly along the insertion axis to implant at least one radioisotope seed wherein the needle assembly comprises a needle coaxially located within a canula and wherein the Z-axis automated motion control system comprises a needle automated motion control system that controls the needle and a canula automated motion control system that controls the canula and [wherein] step (b) comprises:

(b1) using the needle automated motion control system and the canula automated motion control system to repetitively advancing the needle a distance beyond the canula along the insertion axis and then advancing the canula that same distance until the canula is positioned at a desired depth relative to the base plane;

(b2) using the needle automated motion control system to withdraw the needle once the canula is positioned at the desired depth to accept a radioisotope

seed and then advancing the needle to position the radioisotope seed in the canula; and

(c) repeating steps (a) and (b) for a plurality of locations on a base plane perpendicular to the insertion axis.

50. (Cancelled)

51. (Original) A method of operating an automated implantation system having a Z-axis automated motion control system and an X-Y axis automated motion control system that control at least a needle assembly for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

(a) providing an ultrasound probe to establish a base plane for a position of an organ being treated in the brachytherapy procedure;

(b) using the automated implantation system to implant low dose radioisotope seeds in the patient with the Z-axis automated motion control system implanting radioisotope seeds along an insertion axis generally perpendicular to the base plane and the X-Y automated motion control system moving the insertion axis in the base plane;

(c) automatically capturing and storing at least one image from the ultrasound probe for each unique position of the insertion axis in the base plane so as to form a record of the brachytherapy procedure.

52. (Original) A method of operating an automated system for inserting a needle assembly for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure, the needle assembly comprising a needle coaxially located within a canula and the automated system comprising a needle automated motion control system that controls the needle and a canula automated motion control system that controls the canula, the method comprising:

(a) positioning the needle assembly along an insertion axis relative to the patient;

(b) using the needle automated motion control system and the canula automated motion control system to repetitively advancing the needle a distance beyond the canula along the insertion axis and then advancing the canula that same distance until the canula is positioned at a desired depth; and

(c) using the needle automated motion control system to withdraw the needle once the canula is positioned at the desired depth to accept a radioisotope seed and then advancing the needle to position the radioisotope seed in the canula.

53. (Original) The method of claim 52 wherein step (b) is performed such that the distance the needle automated motion control system advances the needle beyond the canula ranges between 0.5 and 2.0 cm.

54. (Original) The method of claim 52 further comprising:

(d) using the canula automated motion control system to withdraw the canula once the radioisotope seed is positioned with the needle automated motion control system keeping the needle in place until the canula is withdrawn.

55. (Original) The method of claim 52 wherein automated system includes at least one cartridge containing a plurality of radioisotopes seeds and a plurality of spacers and wherein step (c) is performed such that a radioisotope seed and a spacer are ejected from the cartridge into the canula as a pair oriented longitudinally along the insertion axis and needle automated motion control system advances the pair along the insertion axis by pushing on the spacer with the needle.

56.-57. (Cancelled)

58. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

means for storing at least a plurality of radioisotope seeds;

a needle assembly;

an ultrasound probe;

first automated means for selectively moving at least the needle assembly along an insertion axis;

second automated means for selectively moving the ultrasound probe in a probe axis generally parallel to the insertion axis; and

a computer processor means operably connected to at least the second automated means and to the ultrasound probe for monitoring a position of an organ being treated in the brachytherapy procedure and selectively adjusting a base plane position of the insertion axis relative to the organ.

59. (Cancelled)

60. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

means for storing at least a plurality of radioisotope seeds;

a needle assembly;

an ultrasound probe;

a first automated means for selectively moving at least the needle assembly along an insertion axis and for selectively ejecting radioisotope seeds from the storage structure into the needle assembly;

a second automated means for selectively moving the ultrasound probe in a probe axis generally parallel to the insertion axis; and

a computer processor operably connected to at least the second automated means, including means for automatically calibrating the second automated means prior to utilizing the ultrasound probe in the brachytherapy procedure.

61. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

means for storing at least a plurality of radioisotope seeds;

a needle coaxially located within a canula;

first automated means for controlling movement of the needle along an insertion axis; and

second automated means for controlling movement of the canula along the insertion axis.

62.-63. (Cancelled)

64. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

means for storing at least a plurality of radioisotope seeds;

a needle assembly;

automated means for selectively moving at least the needle assembly along an insertion axis and selectively ejecting radioisotope seeds from the means for storing into the needle assembly; and

a base station that supports at least the automated means and the needle assembly and positions the insertion axis relative to the patient, the base station including:

a base;

a moveable assembly that includes the insertion axis; and

means operably connected between the base and the moveable assembly for orienting the moveable assembly independently of the base.

65. (Original) The automated implantation system of claim 64 wherein the means for orienting includes:

means for adjusting a vertical height of the moveable assembly relative to the base;

means for pivoting the moveable assembly about a vertical axis relative to the base;

means for adjusting a lateral position of the moveable assembly in relation to the vertical axis; and

means for tilting the moveable assembly relative to a horizontal plane perpendicular to vertical axis.

66. (Original) An automated implantation system for implanting low dose radioisotope seeds in a patient as part of a brachytherapy procedure comprising:

cartridge receiving structure adapted to receive a cartridge containing a plurality of radioisotope seeds;

a needle assembly;

carrier receiving structure adapted to receive a carrier structure containing an ultrasound probe;

first automated means for selectively moving at least the needle assembly along an insertion axis and selectively ejecting radioisotope seeds from the cartridge;

second automated means for selectively moving the ultrasound probe in a probe axis generally parallel to the axis of insertion.

67. (Original) An automated system for controlling insertion of a needle assembly into a patient along an insertion axis, the needle assembly having a needle coaxially located within a canula, the automated system comprising:

base structure that positions the insertion axis relative to the patient, the base structure having a base, a moveable assembly that is orientable independently of the base and includes structure defined along a portion of the insertion axis to receive the needle assembly and, and structure operably connected between the base and the moveable assembly;

a Z-axis automated motion control system that selectively moves the needle assembly along the insertion axis when the needle assembly is positioned in the moveable assembly, wherein the Z-axis automated motion control system comprises:

a needle automated motion control system that controls the needle; and

a canula automated motion control system that controls the canula;

an X-Y axis automated motion control system that selectively moves at least the needle assembly in a plane perpendicular to the insertion axis; and

a computer processor operably connected to at least the Z-axis automated motion control system and the X-Y axis automated motion control system and having a user interface that displays information about the automated implantation system and accepts commands from a user to control the process of inserting the needle assembly.

68. (Original) The automated system of claim 67 wherein the needle automated motion control system and the canula automated motion control system cooperate to initially move the needle and canula along the insertion axis by repetitively advancing the needle a distance beyond the canula and then advancing the canula that same distance.

69. (Original) The automated system of claim 67 wherein the needle automated motion control system and the canula automated motion control system comprise a pair of synchronized lead screw drives.

70. (Original) The automated system of claim 67 wherein the needle assembly includes a force sensor operably connected to at least the needle and to the needle automated motion control system.

71. (Original) The automated system of claim 70 wherein the force sensor senses whether the needle encounters resistance above an expected force for piercing tissue when the needle automated motion control system advances the needle and, in response, the needle automated motion control system stops advancing the needle.

72. (Original) The automated system of claim 71 wherein the force sensor comprises a load cell mounted in a compliant mount at a rear of capstan drive assembly that moves the needle, the compliant mount providing with a minimum travel distance in the event that the needle

encounters resistance above the expected force for piercing tissue that forms a safety buffer to allow the needle to retract.

73. (Original) The automated system of claim 70 wherein the force sensor senses whether the needle has advanced into a non-tissue region and, in response, provides an indication to a user via the user interface that the needle has advanced into the non-tissue region.

74. (Original) A method of operating an automated system for inserting a needle assembly in a patient as part of a medical procedure, the needle assembly comprising a needle coaxially located within a canula and the automated system comprising a needle automated motion control system that controls the needle, a canula automated motion control system that controls the canula and a force sensor operably connected to at least the needle and to the needle automated motion control system, the method comprising:

(a) positioning the needle assembly along an insertion axis relative to the patient;

(b) using the needle automated motion control system and the canula automated motion control system to repetitively advancing the needle a distance beyond the canula along the insertion axis and then advancing the canula that same distance until the canula is positioned at a desired depth; and

(c) in the event that the force sensor senses the needle has encountered resistance above an expected force for piercing tissue when the needle automated motion control system advances the needle in step (b), using the needle automated motion control system to stops advancing the needle.